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Abstracts of Published Papers

Anpac Bio-Medical Science Co., Ltd.

Contents

Meeting Abstracts

Evaluation of a multi-level, multi-parameter detection method for digestive system cancer diagnosis .

Sub-category:
Cancer Prevention

Category:
Cancer Prevention, Genetics, and Epidemiology

Meeting:
2015 ASCO Annual Meeting （Chicago）

Abstrac No:
e12578

Citation:
J Clin Oncol 33, 2015

Author(s): Yefan Zhang, Hong Zhao, Xinyu Bi, Zhen Huang, Jianqiang Cai, Xing Tang, Da Lou, Chris Chang Yu, Xue Dong Du; Cancer Hospital, Chinese Academy of Medical Sciences, Beijing, China; Cancer Institute and Hospital CAMS, Chinese Academy of Medical Sciences, beijing, China; AnPac Bio-Medical Science and Technology Co.,LTD, Shanghai, China; Anpac Bio-Medical Science Co Ltd, Shanghai, China; Anpac Biomedical Science Co.,Ltd., Shanghai, China.

Abstract Disclosures

Abstract

Background: Despite efforts in recent years, major progress in cancer diagnosis remains to be elusive. Existing issues include inability to detect cancer early, relatively low sensitivity and specificity, side effects (for some imaging based technologies), and relatively high costs. In this work, an initial evaluation was carried out on diagnosis of two digestive cancer sites, hepatocellular carcinoma (HCC) and colorectal cancer, using a method named Cancer Differentiation Analysis technology (CDA) which measures both protein and cellular level information in blood in a single test. A performance comparison was made between CDA technology and traditional bio-marker method.
Methods: Blood samples for HCC, colorectal cancer, and control groups were collected, and data were then taken with both bio-marker (serum alpha-fetoprotein (AFP) and carcinoembryonic antigen (CEA)) and CDA methods.

Results: The measured CDA value showed significant statistical difference between the control (20 samples), HCC group (9 samples) and colorectal cancer （6 samples）with P < 0.01, In HCC group, CDA has a sensitivity of 77% (7 of 9) while AFP has a sensitivity of 33% (3 of 9) , and specificity was comparable. In colorectal cancer, CDA has a sensitivity of 83% (5 of 6) while CEA has a sensitivity of 33% (2 of 6) with comparable specificity. Given the limited sample size, more data will be collected to further confirm the initial results.

Conclusions: Based on preliminary, limited data using the new multi-level, multi-parameter blood test method (CDA technology) for HCC and colorectal cancer diagnostics, sensitivity was improved over the traditional bio-marker technology.

Keywords: digestive system cancer diagnosis, colorectal cancer

Meeting Abstracts

Investigations of a new diagnostics technology for hepatocellular carcinoma screening.

Sub-category:
New Targets and New Technologies

Category:
Tumor Biology

Meeting:
2015 ASCO Annual Meeting （Chicago）

Abstrac No:
e22171

Citation:
J Clin Oncol 33, 2015

Author(s): Jiasong Ji, Jingjing Song, Zhongwei Zhao, Jianfei Tu, Xiaoxi Fan, Xing Tang, Da Lou, Hongmei Tao, Yue Lin, Xuedong Du, Chris Chang Yu; Interventional department of Lishui central hospital,the Fifth affiliated hospital of Wenzhou medical university, the Southern Research Institute of Imaging,Zhejiang province,China., Lishui, China; AnPac Bio-Medical Science and Technology Co.,LTD, Shanghai, China; Anpac Bio-Medical Science Co Ltd, Shanghai, China.

Abstract Disclosures

Abstract

Background: A newly developed diagnostic technology named Cancer Differentiation Analysis Technology (CDA) was investigated for hepatocellular carcinoma (HCC) screening. The CDA technology is a blood-sample based, multi-level, multi-param

Methods: Blood samples from patients with HCC (n = 511), cirrhosis (n = 71) and other benign liver diseases (BLD) (n = 46), as well as control subjects (n = 79) were collected in EDTA tubes. CDA values were measured using a CDA device. After removing outliers, the final valid CDA data came from 485 HCC patients, 64 cirrhosis, 44 other benign liver diseases, and 75 controls. All data were analyzed and the results were shown in the table below.

Results: The average CDA of HCC, cirrhosis, BLD, and controls were 53.14, 44.04, 41.90, and 33.90 (rel. units), respectively. The results indicated that HCC could be significantly distinguished from the control, BLD, and cirrhosis (all $p < 0.001$), and the control could be distinguished from BLD and cirrhosis (both $p < 0.001$). The false positives in HCC diagnostic tests could possibly be reduced with this new technology, given statistically significant difference between HCC , and cirrhosis and BLD.

Conclusions: Initial results showed that CDA technology could be a potential candidate for HCC screening.

Table 1 Summary of CDA Test Results.

Group	Number of CDA Data Set	Gender (Male %)	Age Range (year)	Average Age (year)	Median Age (year)	Average CDA (rel. units)	Median CDA (rel. units)	SD of CDA (rel. units)
HCC	485	87	32 - 87	58	58	53.14	53.49	4.03
Hepatocirrhosis	64	83	19 - 81	55	54	44.04	43.83	5.74
BLD	44	68	24 - 75	54	51	41.90	43.43	6.05
Control	75	57	23 - 89	50	49	34.24	33.90	4.76

Meeting Abstracts

Investigations on non-small cell lung cancer screening

Sub-category:
Cancer Prevention

Category:
Cancer Prevention, Genetics, and Epidemiology

Meeting:
2015 ASCO Annual Meeting （Chicago）

Abstrac No:
e12587

Citation:
J Clin Oncol 33, 2015

Author(s): Xuedong Du, Jiasong Ji, Jingjing Song, Zhongwei Zhao, Jianfei Tu, Xiaoxi Fan, Xing Tang, Da Lou, Hongmei Tao, Yue Lin, Chris Chang Yu; AnPac Bio-Medical Science and Technology Co.,LTD, Shanghai, China; Interventional department of Lishui central hospital,the Fifth affiliated hospital of Wenzhou medical university, the Southern Research Institute of Imaging,Zhejiang province,China., Lishui, China; Anpac Bio-Medical Science Co Ltd, Shanghai, China.

Abstract Disclosures

Abstract

Background: Non-small cell lung cancer (NSCLC) is one of the most common cancers in the world. The high mortality rate of lung cancer is partly due to that current image-based technologies are not sensitive enough to screen early lung cancer incidences. A new cancer diagnostics method, named Cancer Differentiation Analysis Technology (CDA hereafter), was developed for diagnosis of lung cancer. In CDA technology, multi-level and multi-parameter data information including protein fragments and cellular information are collected while most existing technologies are single parameter technology, e.g. bio-marker and gene test.

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Methods: Three groups of samples were investigated, NSCLC group (383 samples), non-cancerous lung disease group (103 samples) and control group (149 samples). Samples used in this investigation were whole blood collected via syringe containing EDTA anticoagulant. CDA data were then collected and the differences in CDA data distribution among NSCLC group, non-cancerous lung disease group and control group were investigated.

Results: Test results are shown in Table 1, which exhibited significant statistical difference with P value < 0.05 between any 2 groups in T test. Based on initial data, the sensitivity and specificity of CDA technology for lung cancer test appears to be higher than that of existing technologies, reaching 87.7% and 79.9% respectively.

Conclusions: CDA technology is a promising technology for lung cancer diagnostics. It is able to distinguish control group, non-cancerous disease group and NSCLC group, with sensitivity and specificity higher than existing technologies.

CDA Test Results of Three Groups of Samples

Sample Group	Sample Size	CDA Mean(Rel. Units)	CDA Stdev
Control Group	149	34.09	5.23
Non-Cancerous Disease	103	44.77	9.44
NSCLC Group	383	48.93	7.41

Meeting Abstracts

Investigations of an improved esophageal cancer diagnostics approach

Sub-category:
Investigations of an improved esophageal cancer

Category:
Gastrointestinal (Noncolorectal) Cancer

Meeting:
2015 ASCO Annual Meeting （Chicago）

Abstrac No:
e15059

Citation:
J Clin Oncol 33, 2015

Author(s): Geng Xi Jiang, Junjie Wu, Hua Xiao, Xiao Gang Zhang, Bao Xia Wang, Li Xin Yang, Qiang Li, Xing Tang, Da Lou, Xuedong Du, Chris Chang Yu; Department of Cardiothoracic Surgery, Changhai Hospital of Shanghai, Second Military Medical University, Shanghai, China; "1 State Key Laboratory of Genetic Engineering and Ministry of Education Key Laboratory of Contemporary Anthropology, School of Life Sciences, Fudan University 2Department of Pneumology, Changhai Hospital of Shanghai, Second Military Medical University ", Shanghai, China; Department of Pneumology, Changhai Hospital of Shanghai, Second Military Medical University, Shanghai, China; State Key Laboratory of Genetic Engineering and Ministry of Education Key Laboratory of Contemporary Anthropology, School of Life Sciences, Fudan University, Shanghai, China; Department of Pneumology, Changhai Hospital of Shanghai, Second Military Medical University, Shanghai, China, China; AnPac Bio-Medical Science and Technology Co.,LTD, Shanghai, China; Anpac Bio-Medical Science Co Ltd, Shanghai, China.

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Abstract Disclosures

Abstract

Background: For esophageal cancer, no viable non-invasive detection technologies are available today. In this investigation, a newly developed IVD cancer diagnostic technology named Cancer Differentiation Analysis Technology (CDA) was investigated for esophageal cancer detection. In a CDA technology, multi-level and multi-parameter information is collected using a medical device fabricated by Anpac Bio-Medical Science Co., Ltd. which measures information relating to both protein fragments and cellular signals in blood samples in a single test.

Methods: Blood samples were collected in EDTA vacutainer tubes, with 49 esophageal cancer patients and 303 healthy individuals (control group). CDA data was then collected, and analysis was carried out.

Results: The results showed significant statistical difference between esophageal cancer and control groups with P value < 0.05 (Table 1). Also, CDA values at different stages of esophageal cancer samples showed possible effectiveness using CDA technology for early stage esophageal cancer detection (P value < 0.05 between stage I esophageal cancer and control groups). In addition, using a reasonable cut-off value, its sensitivity and specificity are about 70% and 90%, respectively.

Conclusions: CDA technology is a promising approach for esophageal cancer diagnostics including early stage diagnostics.

Keywords: Esophageal Cancer; CDA

Table 1 CDA Test Results.

Group	Sample Size	CDA Mean (rel. units)	CDA STDEV (rel. units)
Control Group	303	33.7	9.1
Esophageal Cancer Group	49	52.4	11.0

A New Generation Cancer Diagnostic Technology with High Sensitivity and Specificity , Fast Detection Speed ， No Side Effects, Ability for Early Diagnosis, and Cost Efficiency

Meeting:
2015 Nobel Prize Laureate Summit on Biomedical Sciences （Tianjin）

Author(s): Jun Jie Wu(1), (2), Geng Xi Jiang(2), Hua Xiao(2), Xiao Gang Zhang(1), Bao Xia Wang(1), Li Xin Yang (2), Qiang Li(2), Tang Xing(3), Lou Da(3), Hong Mei Tao(3), Yue Lin(3), Xue Dong Du(3), Chris Yu(3)

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(3) AnPac Bio-Medical Science Co., Ltd.

Purpose: Existing cancer diagnosis technologies offer some degree of effectiveness but in general, they lack ability to detect cancer at an early stage, have low sensitivity and specificity for certain cancer sites, and some have side effects. Still, many have low cost efficiency to become viable for cancer screening. A novel, break-through cancer diagnostic technology which overcomes most of the above issues has been developed which adopts a multi-level (including protein and cellular levels), multi-parameter approach (named Cancer Differentiation Analysis Technology (hereafter "CDA")).

Methods: Blood samples were collected in EDTA vacutainer tubes, with 388 samples with pathological information for cancer group and 204 control (non-cancer) samples. CDA data was then collected, and analysis was carried out. Since the goal of this work is primarily focused on assessing the ability of this technology for early stage cancer screening instead of cancer site determination, cancer group included multiple major cancer sites (Table I). Additionally , diagnostic data on a group of 58 liver cancer samples was collected utilizing both CDA technology and bio-marker AFP in order to compare effectiveness of those technologies.

Results: Results: As shown in Table II, CDA technology has ability to detect cancer at stage I. On esophageal cancer, a cancer site which does not have an effective diagnostic method for early detection, CDA is effective in detecting at an early stage (Table III). For both Table I and table II. Test showed that P value between control group and cancer group (for all cancer stage groups) is < 0.001. Tests in additional pre-clinical trial evaluations showed that sensitivity and specificity for a number of cancer sites exceeded 80%, test time is only ~ 5 mins, and cost for screening cover > 10 cancer sites is significantly below that of other technologies . In a head to comparison between CDA technology and bio-marker AFP for liver cancer diagnosis for 58 confirmed liver cancer cases , sensitivity of CDA technology was 79.3% while that for AFP was 55.9% .

Conclusions: CDA technology is a game-changing, effective approach in detecting a number of cancer sites at an early stage with the potential to resolve several existing issues in the field of cancer diagnostics.

Table I Sample description for cancer group

Cases / Group	Stage Ⅰ	Stage Ⅱ	Stage Ⅲ	Stage Ⅳ	Total
Lung Cancer	23	3	9	21	56
Esophageal Cancer	21	27	38	57	143
Cardia Cancer	/	2	4	/	6
Gastric Cancer	/	/	2	/	2
Colon Cancer	1	11	17	19	48
Rectum Cancer	1	6	9	23	39
Liver Cancer	4	8	5	32	49
Pancreatic Cancer	/	1	/	/	1
Oophoroma	/	/	11	13	24
Cervical Cancer	1	2	3	13	19
Prostate Cancer	/	/	/	1	1
Total	51	60	98	179	388

Table II CDA Test Results

	Group Sample Siz	CDA Mean (rel. units)	CDA STDEV (rel. units)
Control Group	204	34.0	34.0
Cancer Stage I	51	47.9	47.9
Cancer Stage II	60	52.5	15.5
Cancer Stage III	98	50.4	13.4
Cancer Stage IV	179	53.1	15.3

Table III CDA Test Results on Esophageal Cancer

	Group Sample Siz	CDA Mean (rel. units)	CDA STDEV (rel. units)
Control Group	204	34.0	7.7
Cancer Stage I	21	50.0	5.1
Cancer Stage II	27	47.9	15.6
Cancer Stage III	38	49.4	12.4
Cancer Stage IV	57	54.8	16.6

荣誉证书

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基于CDA检测技术的非小细胞肺癌检测

会议:
2015年上海市医学会呼吸道学年会

作者：蒋庚西(1)，吴俊杰(1)，肖华(1)，张小刚(1)，王宝霞(1)，
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目的：肺癌是世界上发病率最高，死亡率最高的恶性肿瘤之一。全球每年新发肺癌病例为160万，占所有恶性肿瘤的13%，因肺癌导致的死亡人数每年有140万，占所有恶性肿瘤死亡人数的18%。数据统计表明，五年相对肺癌存活率与肺癌癌症确诊时间有关，早期发现的患者五年相对存活率可达70%左右，而晚期发现的五年存活率小于20%
在本研究中，对于采用一种多层面，多参数，以血液作为检测样本的体外检测技术进行了前临床验证。此技术命名为肿瘤区分分析技术(Cancer Differentiation Analysis Technology (CDA))，采用了多层面多参数包括蛋白片段对肿瘤信号进行收集，处理，分析，从而对于肿瘤的发病做出风险评估。

方法：选取全血样本372例，其中包括健康人群样本303例，非小细胞肺癌50例，肺部疾病样本19例，收集以上样本的CDA检测数据，结合临床资料包括年龄、性别等信息，研究肺癌阳性样本的CDA数据分布与健康人群及非肺癌疾病样本的差异。

结果： CDA肿瘤检测技术能够对三组样本进行区分（P<0.05具有统计学意义），其中肺癌和健康人群的检测灵敏度达到66%，特异性达到90%，明显高于现有体外检测技术。

结论：CDA肿瘤检测技术能够区分肺癌阳性样本、健康人群样本及肺部疾病样本，检测灵敏度特异性明显高于现有诊断或筛查手段，具有无侵入性、成本低、速度快等优点。

Investigation of Breast Cancer Screening Using a Novel In Vitro Diagnostics Technology

Meeting Abstracts

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Investigations of breast cancer screening using a novel in vitro diagnostics technology.

Sub-category:
General Screening

Category:
Risk Assessment, Prevention, Early Detection, and Screening

Meeting:
2015 Breast Cancer Symposium

Abstract No:
13

Poster Board Number:
Poster Session A (Board #D5)

Citation:
J Clin Oncol 33, 2015 (suppl 28S; abstr 13)

Author(s): Hongmei Tao, Xuedong Du, Xing Tang, Yue Lin, Da Lou, Chris Chang Yu; AnPac Bio-Medical Science and Technology Co., LTD, Shanghai, China; Anpac Bio-Medical Science Technology Co., Ltd., Shanghai, China; Anpac Bio-Medical Science Co Ltd, Shanghai, China

Attend this session at the 2015 Breast Cancer Symposium!

Session: Poster Session A: Risk Assessment, Prevention, Early Detection, Screening, and Local/Regional Therapy

Type: Poster Session

Time: Friday September 25, 11:30 AM to 1:00 PM

Location: Yerba Buena Ballroom, Salon 8

Session: Poster Session A: Risk Assessment, Prevention, Early Detection, Screening, and Local/Regional Therapy

Type: Poster Session

Time: Friday September 25, 4:30 PM to 5:30 PM

Location: Yerba Buena Ballroom, Salon 8

Abstract Disclosures

Abstract:

Background: A newly developed in-vitro diagnostic technology named Cancer Differentiation Analysis Technology (CDA) was investigated for breast cancer screening. The CDA technology is a blood-sample based, multi-level, multi-parameter diagnostic method which detects signals from both proteins and cells, in which multiple aspects and parameters of information were collected to improve diagnostic accuracy. **Methods:** Blood samples from breast cancer group (n = 222), and control subjects (n = 204) were collected in EDTA tubes. CDA values were measured using a CDA medical device. The results were shown in Table 1 and Figure 1 below. **Results:** The average CDA values of breast cancer and control groups were 50.43 and 34.03 (rel. units) respectively. The results indicated that breast cancer could be significantly distinguished from the control ($p < 0.001$). Area under ROC curve was 0.914. When Youden Index reached the maximum, sensitivity and specificity was 82.0% and 89.2% respectively. **Conclusions:** Initial results showed that CDA technology could be a potential candidate for breast cancer screening.

Summary of CDA test results.

Group	Sample Size	Age Range	Age Mean	Age Median	CDA Mean (rel. units)	CDA Median (rel. units)	CDA STDEV
Control	204	30 - 84	60	60	34.03	34.81	7.65
Breast Cancer	222	23 - 79	53	54	50.84	50.43	9.69

Other Abstracts in this Sub-Category:

1. Breast MRI screening of women at average risk of breast cancer: An observational cohort study.

Meeting: 2015 Breast Cancer Symposium Abstract No: 1 First Author: Christiane K. Kuhl
Category: Risk Assessment, Prevention, Early Detection, and Screening - General Screening

2. A comparison of clinicopathological characteristics and survival outcomes between symptomatic and screen detected breast cancer in Japanese women.

Meeting: 2015 Breast Cancer Symposium Abstract No: 4 First Author: Hitoshi Inari
Category: Risk Assessment, Prevention, Early Detection, and Screening - General Screening

3. Assessing the value of hepatic arterial phase CT imaging in patients with breast cancer.

Meeting: 2015 Breast Cancer Symposium Abstract No: 5 First Author: David Motiuk
Category: Risk Assessment, Prevention, Early Detection, and Screening - General Screening

基于CDA检测技术的非小细胞肺癌检测

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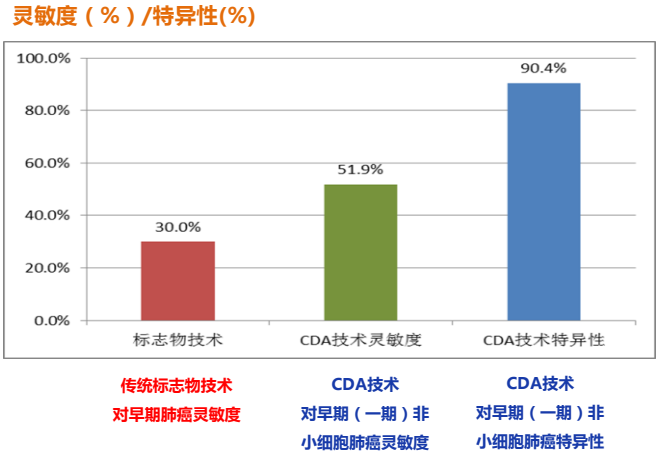
基金项目：上海市科学技术委员会科研计划项目课题任务书（no.12nm0500900），上海国际合作基金项目（14430712002），中国国家自然科学基金（81372236），上海博士后科学基金（12R21411500）

目的

肺癌是世界上发病率最高、死亡率最高的恶性肿瘤之一。全球每年新发肺癌病例为160万，占所有恶性肿瘤的13%，肺癌导致的死亡人数每年有140万，占所有恶性肿瘤死亡人数的18%。数据统计表明，五年相对存活率与肺癌确诊时间有关，早期患者五年相对存活率可达70%左右，晚期患者五年存活率小于20%。本研究采用一种多层面、多参数、以血液作为检测样本的体外检测技术—肿瘤区分分析技术（Cancer Differentiation Analysis Technology，CDA）检测早期肺癌。



方法

选取全血样本372例，其中健康人群303例，早期非小细胞肺癌50例，肺部良性疾病19例，检测以上样本的CDA值，结合临床资料包括年龄、性别及传统标志物（CEA）等信息，研究肺癌人群CDA值与健康人群及肺部良性疾病患者间差异。

结果

CDA肿瘤检测技术能够有效地区别健康人群、非小细胞肺癌和肺部良性疾病三组样本（$p < 0.05$），其中早期肺癌检测灵敏度达到66%，特异性达到90%，明显高于传统标志物检测技术。

结论

CDA肿瘤检测技术对早期肺癌检测的灵敏度及特异性明显高于现有传统标志物，该技术在识别早期肺癌有其独特的优势，有望用于肺癌早期诊断及筛查。